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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/567,544

10/20/2008

Michael Gerrits

7003/49

2509

27774 7590 12/01/2009

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EXAMINER

GEBREYESUS, KAGNEW H

ART UNIT

PAPER NUMBER

1656

MAIL DATE

DELIVERY MODE

12/01/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/567,544	<b>Applicant(s)</b> GERRITS ET AL.	
	<b>Examiner</b> KAGNEW H. GEBREYESUS	<b>Art Unit</b> 1656	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 October 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-12 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

1. Group 1, claim(s) 1-6 are, drawn to a method for the production of a lysate used for cell free protein biosynthesis comprising filtering out an essential translation product from a cell lysate.
2. Group 2, claim(s) 7-10, drawn to a lysate for the cell-free protein biosynthesis wherein the lysate has a reduced activity of one or more essential translation products and a method of using the lysate thereof.
3. Group 3, claims 11 and 12 are drawn to an isolated microorganism or an isolated cell, wherein a genomic sequence, which codes for an essential translation product that reduces the yield of cell-free protein biosynthesis is replaced by a foreign DNA located under a suitable regulatory element, said foreign DNA coding for the essential translation product that additionally contains a marker sequence.

The technical feature linking the inventions of Group 1-3 is a method for the production of protein in a cell free system wherein said process uses an especially formulated cell lysate where an essential translation product is removed from the lysate or reduced from the lysate.

The inventions disclosed in group 1-3 are anticipated or obvious over Short et al. (Effects of Release Factor 1 on in Vitro Protein Translation and the Elaboration of Proteins Containing Unnatural Amino Acids *Biochemistry*, 1999, 38 (27), pp 8808–8819) Short et al teach an S-30 extract derived from *Escherichia coli* that expresses a temperature-sensitive variant of *E. coli* release factor 1 (RF1). Mild heat treatment of the S-30 extract partially deactivated RF1 and improved stop codon (UAG codon) read through by as much as 11-fold. Increasing heat shock time the read-through increased. Short et al do not teach that the RF1 (an essential translation product) was removed from the lysate. However Short et al teach that when RF1 levels were depleted the intrinsic rate of protein synthesis (DHFR synthesis) increases. Therefore it would have been obvious to one of ordinary skill in the art to remove any translation factor such as the RF1 from the lysate using any method including affinity chromatographic methods available at the time of the instant invention to produce the lysate of the instant invention. Therefore the technical feature linking all of the groups is not a special technical feature as defined under PCT Rule 13.1.

Art Unit: 1656

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAGNEW H. GEBREYESUS whose telephone number is (571)272-2937. The examiner can normally be reached on 8:30am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANDREW WANG can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kagnew H Gebreyesus/

Examiner, Art Unit 1656

/Manjunath N. Rao /

Supervisory Patent Examiner, TC1600